

REMARKS

Reconsideration of this application is respectfully request.

A second Supplemental IDS is also included with this response. It contains several references cited in the European Search Report of a related case. The search report was mailed by the European Patent Office to the undersigned on August 26, 2004. An IDS and a one month extension of time is filed concurrently with this amendment and is therefore timely.

I. Claim Status

Claims 1-52 are pending. Claims 3, 4, 5, 6, 7, and 8 have been cancelled without prejudice. Claims 1, 2, 10-36, 38-39, 43-44, 46-47, 49 and 51 have been amended. Claim 1 has been amended to incorporate the definitions for M and V found in original claims 2, 5, 6, 7 and 8. Claim 2 has been amended to incorporate the general Formula I from original claim 1 and the definitions for L and V from original claims 3, 4, 5, 6, 7 and 8. Claims 10-12 have been amended to properly recite dependency in accordance with presently performed amendments. Claims 14-35 have been amended to add the phrase "and pharmaceutically acceptable salts and solvates thereof." Support for this amendment can be found in the specification as filed at page 2 lines 13-14 and page 14 lines 10-11. Claim 36 has been amended to recite the definitions for M and V found in original claims 2, 5, 6, 7 and 8. Claims 38, 39 and 43 have been amended to include the limitation that V is an anti-inflammatory steroid of Formula X or an NSAID subunit selected from among a specific group. Claims 44 and 46 have been amended to include the limitation that V is an antiviral subunit selected from among a specific group. Claims 47, 49 and 51 have been amended to include the limitation that V is an antineoplastic subunit selected from among a specific group. No new matter has been added by these amendments. Support for this amendment comes from claims 2, 3, 4, 5, 6, 7 and 8 as originally filed specification at pages 18-21.

II. Claim Rejections

a. 35 U.S.C. §112 First Paragraph

Claims 1-13 and 36-52 stand rejected under 35 USC §112 first paragraph. The Examiner contends that while being enabled for a compound where M is a macrolide of Formula II, L is a group of Formula IV and V is a group of Formula X and NSAID's, the specification does not reasonably provide enablement for M being a macrolide, V being any non-steroidal anti-inflammatory subunit and L being any linker.

Without conceding that the Examiner's position was correct, claim 1 has been amended to now recite the definitions for M and V originally found in claims 2, 5, 6, 7 and 8. Applicants submit that the recitation of M and V as presented in original claims 2, 5, 6, 7 and 8 and L as originally filed in claim 1 are fully enabled. Applicants submit that many examples of linker molecules are given in the specification and genus of claim 2 and the construction of the present conjugates using these linkers has been both described and exemplified (see pages 17-21 of the specification) Applicants submit that based on this extensive teaching of the present specification a person of ordinary skill can readily select any number of appropriate linker molecules. Accordingly, the breadth of claim 1 is amply enabled by the specification. The specification describes numerous linker moieties which fall under the generic scope of amended claim 1. Claim 2 has been amended to now recite in addition to the definition of M as a macrolide of Formula II the definitions for L being a group of Formula IV originally found in claim 3 or polypeptide originally found in claim 4 and V being a chosen from group of formula X originally found in claim 5; NSAIDs originally found in claim 6; antineoplastic agents originally found in claim 7; and antiviral agents originally found in claim 8. Claim 36 has been amended to recite a process for the preparation of compounds within amended claim 1. Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 38-51 are rejected under 35 U.S.C. 112 first paragraph. The Examiner contends that claim 38-43 are directed to the treatment of inflammatory diseases with a compound of claim 1 where V encompasses not only anti inflammatory steroid subunit of the Formula X and NSAID's

Claim 36 has been rejected under 35 U.S.C. §112 second paragraph for failing to recite definitions for the M, L and V groups. Claim 36 has been amended to recite definitions for the M, L and V groups. Applicants respectfully request reconsideration and withdrawal of this rejection.

Non-statutory Double Patenting Rejection of the Obviousness Type

Claims 1-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of copending Application No. 10/615,010. The Examiner contends that although the conflicting claims are not identical they are not patentably distinct from each other because the compounds of the instant application are encompassed by the compounds of the copending application. Without conceding the Examiner's position, concurrent with the filing of this amendment applicants also file a terminal disclaimer in compliance with 37 CFR 1.32(c).

Claims 1-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of copending Application No. 10/615,716. The Examiner contends that although the conflicting claims are not identical they are not patentably distinct from each other because the compounds of the instant application are encompassed by the compounds of the copending application. Without conceding the Examiner's position, concurrent with the filing of this amendment applicants also file a terminal disclaimer in compliance with 37 CFR 1.32(c).

c. 35 U.S.C. §102(b) Rejection

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Griffin (U.S. Patent 6,566,509) and by WO 97/41255. Claim 1 has been amended to incorporate the limitations found in original claims 2, 5, 6, 7 and 8, which were not so rejected. Amended claim 1 therefore cannot be anticipated by WO 97/41255 or Griffin. Applicants respectfully request removal of this rejection.

Conclusion

It is believed that the application is now in condition for allowance. Favorable action is earnestly solicited. If the Examiner believes a telephonic interview would expedite the prosecution of the instant case, she is invited to call the applicants representative whose contact information appears below.

Dated: December 8, 2004

Respectfully submitted,

By D. Nicholas J. Pate

Nicholas J. Sisti Ph.D. J.D.

Registration No.: 54,453

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 753-6237 (Fax)

Attorneys/Agents For Applicant